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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,882	10/10/2001	Edward M. Nolan	GTI-1320-CON1	8790
35938	7590	01/05/2005	EXAMINER	
BIOTECHNOLOGY LAW GROUP 658 MARSOLAN AVENUE SOLANA BEACH, CA 92075			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/974,882

Applicant(s)

NOLAN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 24-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 24-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 18 October 2004 in response to the Non-Final Office Action mailed 19 March 2004. Claims 21 and 24-26 were considered in the 19 March Office Action. Claims 21 and 26 were amended and claims 27-34 were added in the 18 October Paper. Claims 21 and 24-34 are pending and under consideration.

Response to Amendment

Priority

The priority claim was previously denied because there is no support for a broad negative limitation which excludes plant cells from the scope of the eukaryotic cells used in the method. In reply, Applicant has amended the claim to remove the negative limitation from the claims and added a limitation requiring that the chromosome be introduced into a human or animal cell. In the remarks, Applicant alleges that the claims are supported at paragraphs 0005, 0006, 0017, 0025 and 0026 of the specification. However, upon reviewing the instant specification and parent applications, the Examiner can find no explicit or implicit support for the method claimed comprising "introducing at least one chromosome into a human or animal cell". Although paragraph 0005 recites "human or animal cell" the phrase is found in the following context: "Fluorescence activated cell sorting has been primarily used in studies of human and animal cell lines and the control of cell culture processes. Fluorophore labeling of cells and measurement of the fluorescence can give quantitative data about specific target molecules or subcellular components and their distribution in the cell population." Thus, the method described in paragraph 0005 concerns fluorophore labeling and FACS analysis of labeled cells, not a method

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for introducing at least one chromosome into a human or animal cell. Furthermore, although paragraph 0025 contemplates host cells such as fibroblasts and parenchymal stem cells, which are found in humans and animals, the genus "human or animal cell" embraces cells having widely divergent phenotypes. Thus, the species set forth in the specification do not support the full scope of the genus now recited in the claims. Therefore, the claims do not find support in either the instant application as filed or in the priority documents.

Specification

The specification stands objected to under 35 U.S.C. 132 as containing new matter. As stated in the previous Office Action, the amendment filed 6 January 2004 introduces new matter into the disclosure.

Applicant has amended the specification to incorporate the contents of prior applications 09/453,610 and 60/110,951. There was no statement incorporating these applications by reference in the originally filed disclosure. Although the present application claims benefit of the prior applications, a priority claim under 35 U.S.C. 120 or 119(e) does not amount to an incorporation by reference of the application(s) to which priority is claimed. Therefore, the subject matter incorporated by reference to the prior applications that was not present in the instant application at the time of filing constitutes new matter.

Claim Rejections - 35 USC § 112

Claims 21 and 24-26 stand rejected and newly added claims 27-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

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claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

In response to the rejection of record, Applicant has amended the claims such that they no longer recite the limitation “wherein said cell is not a plant cell” and now recite, “introducing at least one chromosome into a human or animal cell”.

As discussed above, the Examiner can find no explicit or implicit support for the claimed method comprising “introducing at least one chromosome into a human or animal cell”.

Although paragraph 0005 recites “human or animal cell”, it is clear from the context that the method described concerns fluorophore labeling and FACS analysis of labeled cells, not a method for introducing at least one chromosome into a human or animal cell. Likewise, although paragraph 0025 contemplates host cells such as fibroblasts and parenchymal stem cells, which are found in humans and animals, the genus “human or animal cell” embraces cells having widely divergent phenotypes. Thus, the species set forth in the specification do not support the full scope of the genus now recited in the claims. Therefore, the new limitation constitutes new matter.

Rejection of claims 21 and 24-26 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the amendment of the claims such that they are limited to practicing the method *in vitro*.

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Rejection of claims 21 and 24-26 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

Claims 21 and 24-26 stand rejected and newly added claims 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/34436 (hereinafter, '436).

As stated in the Office Action mailed 22 October 2003, the '436 publication teaches a method for introduction of at least one chromosome into a eukaryotic cell comprising contacting at least one chromosome substantially simultaneously with the application of an electric pulse to the cell, wherein the chromosome is encapsulated in a liposome or micelle (see especially claims 21 and 22). The '436 publication further teaches that the cells can be fibroblasts, parenchymal stem cells or hematopoietic stem cells, which are human or animal cells (see especially the paragraph bridging pages 8-9). Thus, the '436 publication teaches all of the limitations of claim 21. Further, the '436 publication teaches the method wherein transformation of the cell with at least one chromosome is verified by FACS according to the limitations of claims 24-26 (see especially the paragraph bridging pages 9-10). Still further, the '436 publication teaches the method wherein the cell is contacted with an encapsulated single chromosome according to claims 27 and 31 (first full paragraph on page 8), and wherein the chromosome comprises 50% protein by weight according to claims 28-30 and 32-34 (third full paragraph on page 8). The '436 publication teaches a method comprising all of the limitations of the instant claims; therefore, the claims are anticipated by the art.

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Although Applicant has sought to overcome the rejection by perfecting the priority claim, the instant claims are not entitled to benefit of the previously filed applications because none of the applications contemplates the method comprising “introducing at least one chromosome into a human or animal cell” (*Id.*).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
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DAVID GUZO
PRIMARY EXAMINER